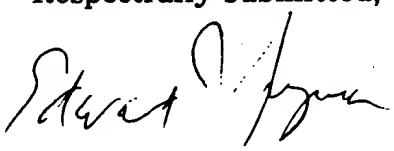
The applicants wish to bring to the attention of the Examiner a Japanese Patent Publication 48-30874 which was cited in the corresponding Japanese application after the U.S. Patent 4,887,606 issued. This reference may be pertinent to the present invention and was not considered by the U.S. Patent and Trademark Office during the examination of the original U.S. Patent 4,887,606. A copy of the Japanese Patent Publication and a translation thereof are attached hereto along with a listing thereof on PTO-1449.

Respectfully submitted,



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Translation from Japanese

(19) JAPANESE PATENT OFFICE (JP)
(11) Japanese Patent Publication (Kokoku) No. 48-30874
(10) Official Gazette for Patent Publications (B2)

(51) Int Cl.:	(52) Japanese Classification
A 61 b	94 A 0 94 A 213.1 100 A 61

(44) Publication Date: September 25, 1973
Number of Inventions: 1
(Total of 3 pages)

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(54) **An Ultrasonic Guide-type Insertion Apparatus for a Medical Paracentesis Tube**

(21) Application No. 42-34045
(22) Filing Date: May 29, 1967
(72) Inventor: Same as applicant
(71) Applicant: Haruo Omizo
(74) Agent: Sadamichi Imamura, Patent Attorney

Brief Description of the Figures

Figures 1 and 2 are practical examples of the present invention. Figure 1 is a vertical cross section of an outside-mounted ultrasonic oscillator type of medical paracentesis needle. Figure 2 is a vertical cross section of an inside-mounted ultrasonic oscillator type of medical paracentesis needle.

Detailed Description of the Invention

The objective of the present invention is to extremely accurately insert or bring close a commonly used medical paracentesis tube (such as a paracentesis needle, a catheter, a probe, or the like) while measuring the depth and direction from the surface of the body by utilizing an ultrasonic beam that has acute directivity with respect to specific arteries, veins, lymph ducts, and other such ducts located deep within the body, as well as to organs that are related to these. The medical paracentesis tube (such as a paracentesis needle) of the present invention is put together such that an extremely small ultrasonic oscillator (made, for example, of barium titanate) is mounted on the tip of a fixed or removable support on the outside (Figure 1) or the inside (Figure 2) of this tube, which also has a high-frequency emitter and receiver for use in oscillator excitation.

Vasal photography, in which a paracentesis tube (such as a paracentesis needle, a catheter, a probe, or the like) is inserted into a duct, and particularly an artery or a vein, and roentgenography is performed while injecting a contrast agent in order to discover any unsound changes in the brain, heart, abdominal organs, limbs, etc., has come into use in recent years as an important examination method. However, sophisticated technology is needed to determine the depth and direction from the surface of the body of ducts (particularly arteries) located deep within the body, and to then perform accurate paracentesis, and if the contrast agent is injected with improper paracentesis, damage to or blockage of the duct or leakage of the contrast agent can injure the nerve tissue, etc., that is present in the surrounding area, which not infrequently can even lead to the death of the patient. The present invention permits this paracentesis to be performed accurately.

The principles of the guiding and insertion of a paracentesis needle of the present invention will now be described along with the method of implementation thereof. When the apparatus of the present invention is used to emit a continuous ultrasonic beam of a specific frequency from the skin surface toward the interior of the

body, if, for instance, any blood vessels are present within this ultrasonic beam, the emitted wave undergoes a Doppler effect due to the movement of the corpuscles flowing through these blood vessels, disturbances in the blood flow, or the pulsation of the vascular wall, so that a reflected wave that has a different frequency from that of the emitted wave can be obtained. After this reflected wave has been converted into an electrical signal with an ultrasonic oscillator, synthetic detection of the emitted signal allows an electrical signal of the difference of the two [waves] to be obtained. After this has been amplified, it can be sent to a speaker or the like to produce a type of buzzing sound that can be detected by ear. When, for instance, the emission frequency is 5 Mc/s, the buzzing sound from an artery is generally about 5000 c/s or less and is an audible sound in which the tone varies with the cardiac cycle, while the buzzing sound from a vein is 2000 c/s or less, and is an audible sound that is not synchronized with the cardiac cycle. These buzzing sounds reach their maximum volume when the ultrasonic beam is directed toward the center of the cross section of the artery in question, and suddenly cease if the ultrasonic beam strays from the artery in question only ever so slightly. Further, the reflected wave from tissue that has no moving portion cannot be heard even if the tissue is in the center of the beam, nor can the buzzing sound resulting from a Doppler effect from nearby members that are out of the line of the beam. Consequently, a paracentesis needle can be inserted into or brought close to the targeted duct, etc., both easily and accurately by combining the paracentesis needle with an ultrasonic oscillator, emitting from an oscillator an ultrasonic beam that has acute directivity, and then guiding the paracentesis needle so as to obtain the maximum volume while constantly receiving the reflected waves from the targeted duct.

However, since the reflected waves from extremely narrow ducts or from ducts that are located at an extremely great depth from the surface of the body are exceedingly weak, unless steps are taken, no buzzing sound can be detected adequately if a synthetic detection with the emitted wave is performed, but inserting into the receiver a circuit that attenuates only the emission frequency results in the reflected waves being made relatively larger, so that a strong buzzing sound can be obtained.

Further, an operation in which blood vessels deep within the brain are ligated or reinforced after performing a craniotomy and after the brain tissue has been removed has been performed in recent years as a treatment method used for preventing hemorrhaging due to the tearing of an arterial knob, etc., or an endocranial hemanglioma in neurosurgery, but this operation can itself be life-threatening, and there is a great possibility that serious after-effects will remain. When the present

paracentesis needle is applied to a case, the tearing of blood vessels or arterial knobs can be prevented with a method in which there is extremely little invasion, wherein a hole of several millimeters in diameter is made in the skull, the paracentesis needle is inserted into the cranium through this hole until it arrives at the diseased member using the buzzing sound from the blood vessel as an indicator, and a resin used fro reinforcing the vascular wall is injected into the surrounding area.

The use of the present apparatus as described above allows a paracentesis tube to be inserted into or brought close to the targeted duct or an organ related to a duct both accurately and safely, which facilitates accurate diagnosis and also allows highly specialized treatments to be performed.

The structure of the present paracentesis tube will now be described while referring to the figures.

Figure 1 shows the ultrasonic oscillator 2 and the oscillator retainer 3 assembled on the outside of the paracentesis tube 1. Therefore, the ultrasonic beam is emitted in the direction of the vertical axis of the paracentesis tube, i.e., the paracentesis direction, so as to encircle the paracentesis tube.

Figure 2 shows the removable ultrasonic oscillator 2 and oscillator retainer 3 assembled on the inside of the paracentesis tube 1. Here, the ultrasonic beam is emitted in the direction of paracentesis from within the tube, and after drawing close to or puncturing the target, only the ultrasonic oscillator and the retainer are removed, and simultaneously with the closing of the removal hole with the valve 5, the connecting hole 7 to the drug injection tube 6 is opened. Finally, 4 is the sending and receiving terminals for the current used in the excitation of the oscillator.

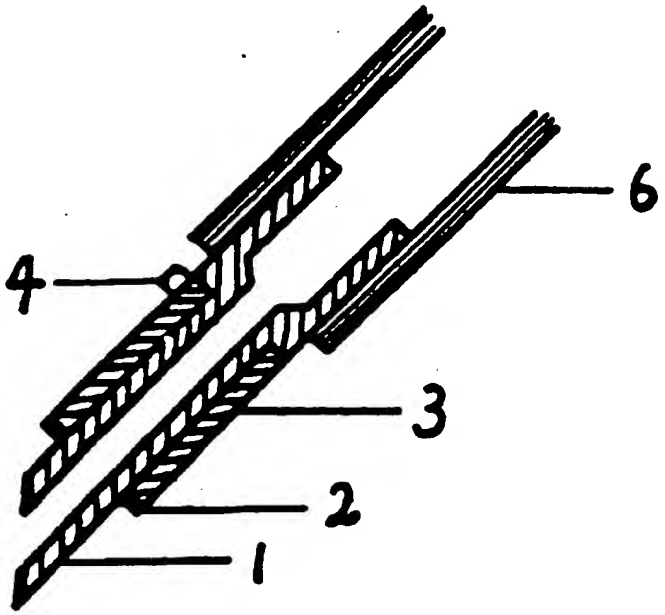
(57) Claims

1 An ultrasonic guide-type insertion apparatus for a medical paracentesis tube, which is characterized by the fact that, in an apparatus that inserts a paracentesis tube into, or guides it close to, a duct using as an indicator a detection signal that results from a Doppler effect of ultrasonic waves, the ultrasonic oscillator 2 is mounted to the support 3, which is attached in a removable fashion or fixed to the paracentesis tube 1, such that the ultrasonic beam is sent in the axial direction of the paracentesis tube, and the drug injection tube 6 is mounted so that it is connected to the paracentesis tube 1.

(56) Cited Publications

Handbook of Ultrasonic Technology (New Revised Edition), October 31, 1966, p. 817 and pp. 831 to 832, published by Nikkan Kogyo Shinbun-sha.

Figure 1



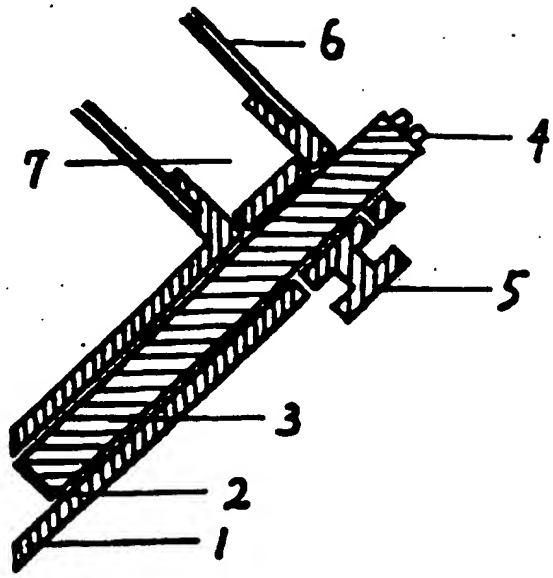


Figure 2

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the reissue application of	)	Reissue of U.S. 4,887,606
PAUL G. YOCK et al.	)	Examiner
For APPARATUS FOR USE IN CANNULATION OF BLOOD VESSELS	)	Group Art Unit
Serial No.	)	
Filed *[Concurrently herewith]*	)	
Atty. Docket 18000.5003.3	)	

December 17, 1991

CROSBY, HEAFEY, ROACH & MAY
Los Angeles, California

CERTIFICATE OF MAILING UNDER 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service in an postage prepaid envelope as "Express Mail Post Office to Addressee" using Mailing Label No. EB 036 477 650
This correspondence is addressed to: Commissioner of Patents and Trademarks, Washington, DC 20231
Such service was made on December 17, 1991

December 17, 1991
Cynthia Anne Snyder

PRELIMINARY AMENDMENT

The Commissioner
United States Patent
and Trademark Office
Washington, DC 20231

Dear Sir:

Please preliminarily amend the above-identified application for the reissue of U.S. Patent 4,887,606 as follows:

IN THE SPECIFICATION

In column 2, line 2, and in column 3, lines 22 and 25 change "trocar" at

each occurrence to --stylet--.

In column 2, line 3, insert the following:

--FIG. 5 is a partial cross-sectional view of a needle and an alternative stylet.

FIGS. 6 and 7 are additional alternative embodiments of stylets in accordance with the invention.--

In column 3, line 18, delete "this" and insert --the--, and after "embodiment" insert --shown in FIG. 5--.

In column 3, line 46, change "container portion" to --syringe-. and in line 47 change "container" to --syringe--.

IN THE CLAIMS

Please amend claim 1 as follows:

1. (Amended) Apparatus for use in cannulation of blood vessels comprising

a hollow needle having an inner lumen, a sharpened distal end for penetrating tissue and a proximal end adapted to receive a syringe,

a stylet having proximal and distal ends, being positioned within the inner lumen of said needle and being spaced from the interior of said needle to facilitate back flow of blood when a blood vessel in penetrated, the stylet including an ultrasound transducer supported at [one] the distal end for transmitting and receiving ultrasonic waves through the sharpened end of said needle,

[a support rod for supporting said transducer, means attaching said transducer to said support rod, coaxial] electrical conductors associated with said [support rod] stylet for transmitting electrical signals to and from said transducer, including a [wire] first conductor extending through said [support rod] stylet electrically connected with a back surface of said transducer, and a [metal] second conductor on the surface of said [rod] stylet electrically [interconnected] connected with a front surface of said transducer[, said metal conductor and support rod being spaced from said needle to facilitate back flow of blood when a blood vessel is penetrated], and

a syringe portion detachably attached to the proximal end of said needle.

In claim 6, line 1, change "trocar" to --stylet--

Please add the following new claims:

7. Apparatus for use in cannulation of blood vessels comprising a hollow needle having an inner lumen, a sharpened distal end for penetrating tissue

a stylet having proximal and distal ends, being positioned within the inner lumen of said needle, having an inner lumen to facilitate back flow of blood when the distal end of the needle is disposed within the blood vessel, the stylet including an ultrasound transducer means supported at the distal end of the stylet for transmitting and receiving ultrasonic waves through the sharpened end of said needle,

electrical conductors associated with said stylet for transmitting electrical signals to and from said transducer means, including a first conductor having a cylindrical shape and being electrically connected with a first surface of said transducer means, and a second conductor being electrically connected with a second surface of said transducer.

8. The apparatus of claim 7 wherein the stylet has an inner lumen extending longitudinally therein formed by the cylindrically shaped conductor and the ultrasound transducer means is secured to the end of the cylindrically shaped conductor.

9. The apparatus of claim 8 wherein the ultrasound transducer means has a circular shape.

10. The apparatus of claim 9 wherein the ultrasound transducer means has a central aperture which is in communication with the inner lumen of the stylet.

11. The apparatus of claim 7 wherein the stylet is disposed within the inner lumen of the hollow needle with the second conductor electrically connected to the hollow needle.

12. The stylet of claim 7 wherein the second conductor is stainless steel tubing.

13. The stylet of claim 7 wherein a syringe is releasably secured to the proximal end of the needle.

14. A method for guiding a hollow needle through tissue into a blood vessel of a patient comprising:

a) providing an apparatus which includes:

a hollow needle having an inner lumen, a sharpened distal end for penetrating tissue and a proximal end,

an elongated stylet having proximal and distal ends positioned within the inner lumen of said needle and including an ultrasonic transducer means secured to the distal end of the stylet for transmitting and receiving ultrasonic waves through the sharpened distal end of said needle having a front surface and a rear surface, electrical conductors associated with said stylet for transmitting electrical signals to and from said transducer means, including a first electrical conductor extending through the interior of the stylet and being electrically connected to one surface of said transducer means, and a second electrical conductor being electrically connected to a second surface of said transducer means;

b) penetrating the skin of the patient with the sharp distal end of the needle and advancing the needle through the tissue of the patient;

c) emitting ultrasonic waves from the ultrasound transducer means on the distal end of the stylet, receiving reflected ultrasonic waves by said transducer means and generating a signal representing the reflected ultrasonic waves; and

d) adjusting the direction of the distal sharpened end of the needle as it is advanced through the patient's tissue based upon the

received ultrasonic waves to direct the sharpened distal end of the needle into a blood vessel of the patient, the approach of the needle to a blood vessel characterized by an increase in the intensity of the signals representing the reflected ultrasonic waves and the positioning of the sharpened distal end of the needle within a blood vessel characterized by a substantial increase in the signal representing the reflected ultrasonic waves.

15. The method of claim 14 wherein a syringe is secured to the proximal end of the needle and a back pressure is applied on the syringe to effect a negative pressure within the needle to create a back flow of blood into the syringe when the sharpened distal end of the needle is disposed within a blood vessel.

16. An apparatus for use in the cannulation of a blood vessel comprising:

a hollow needle having an inner lumen, a sharpened distal end for penetrating tissue and a proximal end, and

a stylet having proximal and distal ends, being positioned within the inner lumen of said needle and being spaced from the interior of said needle to facilitate back flow of blood when the needle is positioned within a blood vessel, the stylet including an ultrasound transducer

means supported at the distal end of the stylet for transmitting and receiving ultrasonic waves through the sharpened end of said needle electrical conductors associated with said stylet for transmitting electrical signals to and from said transducer means, including a first conductor extending through said stylet electrically connected with a first surface of said transducer, and a second conductor disposed about the first conductor electrically connected with a second surface of said transducer means.

17. The apparatus of claim 16 wherein a syringe is releasably secured to the proximal end of the needle.

18. The apparatus of claim 16 wherein the first conductor has a cylindrical shape, is disposed about the second conductor and is connected to the front surface of the transducer means and the second conductor is connected to the back surface of the transducer means.

19. The apparatus of claim 1 wherein the first conductor has a cylindrical shape, is disposed about the second conductor and is connected to the front surface of the transducer means and the second conductor is connected to the back surface of the transducer means.

20. A stylet having proximal and distal ends adapted to positioned within an inner lumen of a needle and dimensioned to be spaced from the interior of said needle to facilitate back flow of blood when the needle is positioned within a blood vessel, the stylet comprising:

a) an elongated body having proximal and distal ends;

b) an ultrasound transducer means supported at the distal end of the elongated body for transmitting and receiving ultrasonic waves through the sharpened end of said needle; and

c) electrical conductors associated with said stylet for transmitting electrical signals to and from said transducer means, including a first conductor wire extending through said stylet which is electrically connected with a rear surface of said transducer means, and a second conductor of essentially cylindrical shape disposed about the first conductor electrically connected with a front surface of said transducer means.

22. The stylet of claim 21 wherein solid insulation is disposed between the first and second conductors.

23. A kit for use in the cannulation of a blood vessel comprising:

a) a hollow needle having an inner lumen, a sharpened distal end for penetrating tissue and a proximal end; and

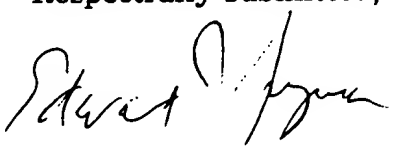
b) a stylet having proximal and distal ends adapted to be positioned within the inner lumen of said needle and being spaced from the interior of said needle to facilitate back flow of blood when the needle is positioned within a blood vessel, the stylet including an ultrasound transducer means supported at the distal end of the stylet for transmitting and receiving ultrasonic waves through the sharpened end of said needle, electrical conductors associated with said stylet for transmitting electrical signals to and from said transducer means, including a first conductor extending through said stylet electrically connected with a first surface of said transducer, and a second conductor disposed about the first conductor electrically connected with a second surface of said transducer means.

REMARKS

The patentees respectfully request that the above amendments to the specification and the claims, including the addition of new claims, be considered by the Examiner during the initial examination of this application. It is believed that the amended and the new claims define patentable subject matter and consideration and an early allowance thereof are respectfully requested.

The applicants wish to bring to the attention of the Examiner a Japanese Patent Publication 48-30874 which was cited in the corresponding Japanese application after the U.S. Patent 4,887,606 issued. This reference may be pertinent to the present invention and was not considered by the U.S. Patent and Trademark Office during the examination of the original U.S. Patent 4,887,606. A copy of the Japanese Patent Publication and a translation thereof are attached hereto along with a listing thereof on PTO-1449.

Respectfully submitted,



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(51) Int Cl.:	(52) Japanese Classification
A 61 b	94 A 0 94 A 213.1 100 A 61

(44) Publication Date: September 25, 1973
Number of Inventions: 1
(Total of 3 pages)

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(54) **An Ultrasonic Guide-type Insertion Apparatus for a Medical Paracentesis Tube**

(21) Application No. 42-34045
(22) Filing Date: May 29, 1967

(72) Inventor: Same as applicant
(71) Applicant: Haruo Omizo
(74) Agent: Sadamichi Imamura, Patent Attorney

Brief Description of the Figures

Figures 1 and 2 are practical examples of the present invention. Figure 1 is a vertical cross section of an outside-mounted ultrasonic oscillator type of medical paracentesis needle. Figure 2 is a vertical cross section of an inside-mounted ultrasonic oscillator type of medical paracentesis needle.

Detailed Description of the Invention

The objective of the present invention is to extremely accurately insert or bring close a commonly used medical paracentesis tube (such as a paracentesis needle, a catheter, a probe, or the like) while measuring the depth and direction from the surface of the body by utilizing an ultrasonic beam that has acute directivity with respect to specific arteries, veins, lymph ducts, and other such ducts located deep within the body, as well as to organs that are related to these. The medical paracentesis tube (such as a paracentesis needle) of the present invention is put together such that an extremely small ultrasonic oscillator (made, for example, of barium titanate) is mounted on the tip of a fixed or removable support on the outside (Figure 1) or the inside (Figure 2) of this tube, which also has a high-frequency emitter and receiver for use in oscillator excitation.

Vasal photography, in which a paracentesis tube (such as a paracentesis needle, a catheter, a probe, or the like) is inserted into a duct, and particularly an artery or a vein, and roentgenography is performed while injecting a contrast agent in order to discover any unsound changes in the brain, heart, abdominal organs, limbs, etc., has come into use in recent years as an important examination method. However, sophisticated technology is needed to determine the depth and direction from the surface of the body of ducts (particularly arteries) located deep within the body, and to then perform accurate paracentesis, and if the contrast agent is injected with improper paracentesis, damage to or blockage of the duct or leakage of the contrast agent can injure the nerve tissue, etc., that is present in the surrounding area, which not infrequently can even lead to the death of the patient. The present invention permits this paracentesis to be performed accurately.

The principles of the guiding and insertion of a paracentesis needle of the present invention will now be described along with the method of implementation thereof. When the apparatus of the present invention is used to emit a continuous ultrasonic beam of a specific frequency from the skin surface toward the interior of the

body, if, for instance, any blood vessels are present within this ultrasonic beam, the emitted wave undergoes a Doppler effect due to the movement of the corpuscles flowing through these blood vessels, disturbances in the blood flow, or the pulsation of the vascular wall, so that a reflected wave that has a different frequency from that of the emitted wave can be obtained. After this reflected wave has been converted into an electrical signal with an ultrasonic oscillator, synthetic detection of the emitted signal allows an electrical signal of the difference of the two [waves] to be obtained. After this has been amplified, it can be sent to a speaker or the like to produce a type of buzzing sound that can be detected by ear. When, for instance, the emission frequency is 5 Mc/s, the buzzing sound from an artery is generally about 5000 c/s or less and is an audible sound in which the tone varies with the cardiac cycle, while the buzzing sound from a vein is 2000 c/s or less, and is an audible sound that is not synchronized with the cardiac cycle. These buzzing sounds reach their maximum volume when the ultrasonic beam is directed toward the center of the cross section of the artery in question, and suddenly cease if the ultrasonic beam strays from the artery in question only ever so slightly. Further, the reflected wave from tissue that has no moving portion cannot be heard even if the tissue is in the center of the beam, nor can the buzzing sound resulting from a Doppler effect from nearby members that are out of the line of the beam. Consequently, a paracentesis needle can be inserted into or brought close to the targeted duct, etc., both easily and accurately by combining the paracentesis needle with an ultrasonic oscillator, emitting from an oscillator an ultrasonic beam that has acute directivity, and then guiding the paracentesis needle so as to obtain the maximum volume while constantly receiving the reflected waves from the targeted duct.

However, since the reflected waves from extremely narrow ducts or from ducts that are located at an extremely great depth from the surface of the body are exceedingly weak, unless steps are taken, no buzzing sound can be detected adequately if a synthetic detection with the emitted wave is performed, but inserting into the receiver a circuit that attenuates only the emission frequency results in the reflected waves being made relatively larger, so that a strong buzzing sound can be obtained.

Further, an operation in which blood vessels deep within the brain are ligated or reinforced after performing a craniotomy and after the brain tissue has been removed has been performed in recent years as a treatment method used for preventing hemorrhaging due to the tearing of an arterial knob, etc., or an endocranial hemanglioma in neurosurgery, but this operation can itself be life-threatening, and there is a great possibility that serious after-effects will remain. When the present

paracentesis needle is applied to a case, the tearing of blood vessels or arterial knobs can be prevented with a method in which there is extremely little invasion, wherein a hole of several millimeters in diameter is made in the skull, the paracentesis needle is inserted into the cranium through this hole until it arrives at the diseased member using the buzzing sound from the blood vessel as an indicator, and a resin used fro reinforcing the vascular wall is injected into the surrounding area.

The use of the present apparatus as described above allows a paracentesis tube to be inserted into or brought close to the targeted duct or an organ related to a duct both accurately and safely, which facilitates accurate diagnosis and also allows highly specialized treatments to be performed.

The structure of the present paracentesis tube will now be described while referring to the figures.

Figure 1 shows the ultrasonic oscillator 2 and the oscillator retainer 3 assembled on the outside of the paracentesis tube 1. Therefore, the ultrasonic beam is emitted in the direction of the vertical axis of the paracentesis tube, i.e., the paracentesis direction, so as to encircle the paracentesis tube.

Figure 2 shows the removable ultrasonic oscillator 2 and oscillator retainer 3 assembled on the inside of the paracentesis tube 1. Here, the ultrasonic beam is emitted in the direction of paracentesis from within the tube, and after drawing close to or puncturing the target, only the ultrasonic oscillator and the retainer are removed, and simultaneously with the closing of the removal hole with the valve 5, the connecting hole 7 to the drug injection tube 6 is opened. Finally, 4 is the sending and receiving terminals for the current used in the excitation of the oscillator.

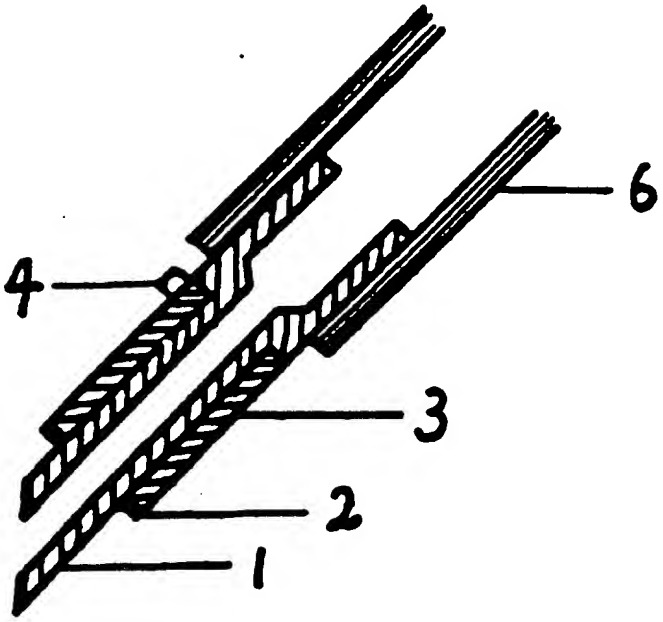
(57) Claims

1 An ultrasonic guide-type insertion apparatus for a medical paracentesis tube, which is characterized by the fact that, in an apparatus that inserts a paracentesis tube into, or guides it close to, a duct using as an indicator a detection signal that results from a Doppler effect of ultrasonic waves, the ultrasonic oscillator 2 is mounted to the support 3, which is attached in a removable fashion or fixed to the paracentesis tube 1, such that the ultrasonic beam is sent in the axial direction of the paracentesis tube, and the drug injection tube 6 is mounted so that it is connected to the paracentesis tube 1.

(56) Cited Publications

Handbook of Ultrasonic Technology (New Revised Edition), October 31, 1966, p. 817 and pp. 831 to 832, published by Nikkan Kogyo Shinbun-sha.

Figure 1



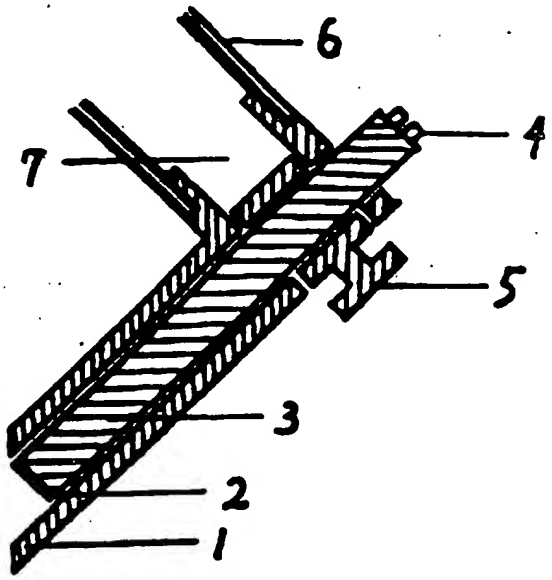


Figure 2